

**CALIFORNIA CABG OUTCOMES REPORTING PROGRAM
CLINICAL ADVISORY PANEL MEETING**

Sutter Square Galleria
2901 K Street, Room 201
Sacramento, CA 95816

**JULY 26, 2004
9:00 a.m. to 3:00 p.m.**

MEETING MINUTES

In Attendance

Clinical Advisory Panel Members:

Andrew Bindman, M.D.
Ralph Brindis, M.D., F.A.C.C.
Robert Brook, M.D., Sc.D.
Cheryl Damberg, Ph.D.
Coyness Ennix, Jr., M.D.
Keith Flachsbar, M.D.
Frederick Grover, M.D.
James MacMillan, M.D.

Panel Members Absent:

Timothy Denton, M.D., F.A.C.C.

CCORP Consulting Cardiologist:

Anthony Steimle, M.D.

OSHPD Staff:

David Carlisle, M.D., Ph.D.
Joseph Parker, Ph.D.
Zhongmin Li, Ph.D.
Mike Kassis
Jacquelyn Paige
Raquel Lothridge
Hilva Chan
Herbert Jew
Niya Fong
Christie Westover
Brenda Hofer
Jesse Kerr

Other Attendees:

Richard Kravitz, M.D., Ph.D.,
University of California, Davis

Introduction

Dr. Robert Brook, Chairman, called the meeting to order at approximately 9:00 a.m. Introductions were made and minutes from the January 8th, 2003 CAP meeting were approved.

Dr. Joseph Parker provided the program director's report. Since the last CAP meeting, OSHPD has experienced staffing challenges including the departure of Dr. Loel Solomon, Deputy Director for the Healthcare Outcomes Center. When Dr. Solomon left, the Deputy Director position was taken away in a sweep of all vacant positions in the state. Due to the state's budget constraints, OSHPD has not been able to hire any new staff. However, through a contract with UC Davis, the Office was able to bring on a full time health services researcher, Zhongmin Li, who is an adjunct faculty member at UC Davis.

The CAP expressed concern regarding the Office's ability to accomplish its goals given the aforementioned staffing challenges and the state's budget constraints. Dr. Parker expressed his confidence in the CCORP program's stability and is optimistic that a recent two-year contract with UC Davis, as well as the ability to bring on at least one additional staff member later in the year, should ensure that CCORP and CCMRP reports are released to the public in a timely fashion, though some activities are behind schedule.

Dr. Ennix and other CAP members expressed interest in seeing the CCORP budget. Dr. Parker said he could make the budget available to them.

The CAP was concerned that there might be significant changes in the statistical methodology used for CCORP reports versus that used for CCMRP reports given that OSHPD is now working with UC Davis, not PBGH, on report production. Dr. Parker explained that Beate Danielsen, Ph.D., who worked with OSHPD on CCMRP reports for several years, was contracted by PBGH and is now under contract with UC Davis. Dr. Danielsen will continue to work with OSHPD and UC Davis on the CCORP reports. Furthermore, the CAP will be involved in making decisions regarding the format and content of CCORP reports.

The first CCORP hospital level report is scheduled for release in July 2005. The Office is also required by law to analyze the impact of public reporting on the quality of surgical outcomes and patient selection. CCORP reports will also analyze the relationship between volume and outcome. This has not been a major component of previous reports, but all CCMRP reports have touched on the volume issue.

Dr. Parker reminded the CAP that their primary responsibilities include: recommending which data elements we should collect, reviewing and approving the risk adjustment model, reviewing physician appeals and consulting on report materials.

CCORP Update

CCORP has received all hospital data for 2003. One hundred and twenty-one (121) hospitals submitted data and two hospitals closed during the year. Hospitals are getting better at submitting their data. More data is now being received by the deadline and is being accepted the first time. CCORP gets better quality data from the thirty hospitals that use the CCORP tool, since it's able to incorporate all the data quality checks in the software.

Dr. Parker provided the CAP descriptive statistics on CABG volume and mortality from 1997 to 2003. The mean volume of isolated CABG surgeries per hospital in California is lower than that of other states that do public reporting (i.e. Pennsylvania, New Jersey, and New York). The mean isolated CABG volume per hospital in California is 176 versus 550 in New Jersey, 490 in New York, and 270 in Pennsylvania. California has many small volume hospitals, which will impact how we report the data. The mean volume per surgeon in California is 73 with 1 as the minimum number of cases and 361

as the maximum number of cases. This compares to a little over 100 for all other states. Seventy-three (73) surgeons in California have CABG annual volumes less than 30.

The volume of percutaneous coronary interventions (PCIs) has gone up approximately 35 percent between 1997 and 2003. During this same time period, the volume of isolated CABG surgeries has decreased by approximately 24 percent. California's observed mortality rate for isolated CABG surgeries (2.71 percent) is higher than New York's (2.32 percent), New Jersey's (2.22 percent) and Pennsylvania's (2.00 percent), though some of this may be attributable to slightly different definitions of isolated CABG across the states.

Dr. Brook emphasized that the context for CABG reporting is getting tough because CABG volume is decreasing and improving the level of care will only save an additional 100 lives per year in California. Given this trend, questions may arise at the state level regarding the necessity of this program and there may be interest in focusing on something else (i.e. percutaneous coronary intervention).

Timeline for producing the first CCORP hospital level report was presented. The report is scheduled for release in July 2005. When the report is complete the data will be two years old, which is still more timely than New York's report and will be more timely than the CCMRP reports. CAP approved the timeline.

CCORP Discussion Items

Isolated CABG definition and Case Review

- Motion passed to retain definition of CABG plus TMR as an isolated CABG.
- Motion passed to define CABG plus certain "mini" maze procedures – isolating the pulmonary vein, amputation of left atrial appendix, and other procedures that do not require opening the left atrium – as an isolated CABG [defer to Dr. Steimle for official definition]. This is a revision to the current definition.
- Motion passed to define thymectomy plus CABG as an isolated CABG.
- Motion passed to define thyroidectomy plus CABG as an isolated CABG.
- Motion passed that lung resection exclusion be redefined to include only procedures where segmental resection or lobectomy was performed. Many emphysematous blebs (currently excluded) would not meet this criterion. Cases are considered to be isolated CABG surgeries unless it is shown that a lung procedure, at least at the level of segmental resection or lobectomy, occurred at the same time [defer to Dr. Steimle for official definition].

The CAP reviewed the following three CCORP cases and agreed that:

- Foot amputation with CABG is a non-isolated CABG. A motion was passed to define CABG plus amputation of any part of an extremity as a non-isolated CABG.

- “Staged” carotid endarterectomy with CABG is an isolated CABG in this instance since these two procedures were not performed under the same anesthesia.
- CABG with bullectomy using GIA pericardial stapling device is an isolated CABG. Motion passed that unless the lung procedure is at the level of segmental resection or lobectomy, CABG plus lung procedure is an isolated CABG [defer to Dr. Steimle for official definition].

New Outcome Measures

CAP members suggested several possible studies regarding process measures and appropriateness. The CAP is very interested in studying process measures (i.e. IMA utilization and the prescription of lipid or statin drugs on discharge) to determine if hospitals and surgeons are practicing up-to-date medicine. Given that 18 percent of people with CABG surgeries are readmitted to the hospital, Dr. Brook thinks it would be interesting to study the stability of patients at time of discharge and the practices of hospitals and surgeons at time of discharge. There was some concern among CAP members regarding the burden on hospitals to collect process measures that are not already being collected by STS. The committee asked OSHPD to identify a series of process measures that could be considered as additional data elements in the future.

The CAP is also very interested in studying appropriateness. Dr. Damberg feels it is important to provide guidance to patients as to what constitutes the need for surgery. Currently we do not help patients decide whether they should be managed medically and Dr. Damberg thinks CCORP could make a significant contribution in that area. Dr. Brook also feels it is important to reassure the consumer, either for the state as a whole or for particular regions of the state, that there is no problem with appropriateness. Furthermore, it would also be nice to know whether people that the scientific evidence suggests would benefit from bypass surgery, as opposed to interventional cardiology, are being offered CABG surgery.

Dr. Brook likes the idea of studying the under-utilization of CABG surgery in California given the number of uninsured persons and the pressure to increase volume. He also thinks it is important to study overuse in light of a study done in New York that shows the unreliability of one person reading an angiogram and the fact that a large number of people were operated on that didn't have the disease. According to Dr. Brook, the biggest patient safety question that is unanswered is the under and overuse of effective, safe surgical procedures. Dr. Brook is also very interested in talking to people after CABG surgery to determine their quality of life. For instance, do people go back to work, can they walk up a flight of stairs, are they breathless, did their angina go away?

Given that CCORP does not have the resources or the time to accomplish these studies at this time, Dr. Bindman suggested that the introduction to the first CCORP report clearly state what the report addresses and what it does not. In other words, the introduction should state that the report includes patients who undergo isolated CABG

surgery and reports on their death. It does not say anything about what is going on in regards to morbidity or appropriateness. Framing the introduction of the CCORP report in this way may create a political process for conducting additional research. There was consensus among CAP members to ask OSHPD to write a contract requiring UC Davis to write a policy piece regarding what should be the next step beyond reporting mortality for CABG surgery.

The CAP agreed to let staff proceed with collecting complication measures that STS already collects, though they were interested in seeing progress in the areas of process measures and appropriateness. Complication measures will start being collected in 2005 and will require training hospital data abstractors. The CAP expressed concern over defining and measuring complication measures (i.e. stroke) and the argument was made that collecting process measures would be much easier on the hospitals. Although staff will proceed with collecting complication measures, the CAP wants to revisit this subject again in the future.

CAP discussed whether or not to include salvage cases in publicly reported risk-adjusted mortality rates for surgeons and hospitals. The CAP would like to know if the number of salvage cases has decreased since CCMRP. It was suggested that salvage cases be included in the hospital level report, but not in the surgeon level report. The CAP is interested in having UC Davis conduct a study on how salvage cases affect low volume surgeons. It was decided to postpone this decision until more data is available.

CAP approved a motion to replace in-patient mortality with operative mortality as an outcome measure. This includes all deaths within 30 days of CABG surgery regardless of whether the patient is in the hospital or has been discharged **and** all in-hospital deaths. This will require waiting for the vital statistics death file to become available in November or December to allow linkage with CCORP data. Dr. Parker stated this should result in little or no delay of the first CCORP public report.

STS Data Elements, Changes and Deletions Affecting CCORP Variables

Dr. Parker expressed concern that the continued need to keep up with STS definition changes could result in large program inefficiencies and increased data collection costs for hospitals. Dr. Brook countered that we should not let our desire to be in parallel with STS drive decisionmaking – our responsibility to the principles that the legislation sets out should guide our decisionmaking. The CAP agreed that CCORP will adopt minor definitional changes to variables made by STS. The CAP also agreed that CCORP will drop those data elements that STS dropped if they are not part of the CCORP risk model (e.g. Canadian Cardiovascular Society Classification). There was no resolution in regards to process measures that STS changed (i.e. cardiopulmonary bypass used, conversion to cardiopulmonary bypass), with Dr. Grover offering to bring clarification to some questions concerning recent STS data element definition changes.

Audit Strategy for 2003 Data

CCORP is modeling their audit strategy based on the audits conducted for CCMRP. The intent is to audit one third of the hospitals (40) and approximately 25 percent of their cases. Based on the risk model at the time of audit, all low and high outlier hospitals, as well as those hospitals that are close to the fence, will be audited. In addition, another third or quarter of the hospitals that fall in the middle will be audited. All deaths at each hospital are audited. If discrepancies are found, the auditors are considered right and the data is changed.

The CAP was impressed with the thoroughness of the audit strategy. The CAP emphasized the importance of the audit process and that all hospitals with better than expected performance and worse than expected performance need to be audited prior to public reporting. There was interest on the committee to audit all hospitals with high expected values, even if their observed to expected ratio does not make them an outlier. There was concern expressed by the CAP that, over time, all hospitals get audited in an effort to help them improve their data quality. Dr. Parker recommended that if a hospital in the middle was audited under CCMRP they are not audited under CCORP for 2003.

The CAP approved the overall audit strategy and agreed to let the program's statisticians handle the details of implementation. CCORP will audit all better than and worse than expected hospitals and a sample of hospitals in the middle.

CCMRP Discussion Items

There was discussion on whether or not to proceed with the CCMRP public report without auditing the data. Dr. Brindis and Dr. Grover expressed serious concerns over releasing the data without an audit. Dr. Parker explained that since the DDR process accurately verifies all deaths and ensures that all isolated CABGs (including deaths) have been submitted to CCMRP, for all hospitals, it even improves on an audit in some respects. Motion was passed to release the 2000-2002 CCMRP report without an audit with one abstention. The CAP emphasized the need to provide a very careful explanation in the preamble of the report regarding the verification process.

Preliminary Risk Model and Results

CAP approved the risk model for CCMRP.

Isolated CABG Cases Submitted by Hospitals

The CAP reviewed the following CCMRP cases and agreed that:

- Perforated left ventricular with CABG: isolated CABG.
- CABG with coronary endarterectomy of LAD, left atriotomy, and thoracentesis: isolated CABG.

- CABG with femoral artery/vein repair: isolated CABG.
- CABG with intramyocardial LAD, dissection, and myocardial bridging: isolated CABG.

Dr. Brook emphasized the need for a standardized appeals form that requires hospitals to state what is unique about the case they are appealing.

Cases Requested for Exclusion

The CAP reviewed the following three cases and decided that they should be included in the data submission:

- Patient with rare dermatological condition, leg amputation (2001 CCMRP).
- Patient with factor XI deficiency – hematological disorder (2001 CCMRP).
- Patient with post-catheterization clot blockage of coronary arteries- eight-month old stent (2003 CCORP).

The CAP would like to schedule the next meeting as soon as possible. During the next meeting, the CAP will approve the 2003 CCORP risk model, discuss the surgeon level report, and review the CCORP report.

CAP members would like a copy of the PowerPoint presentation from today's meeting.

Meeting was adjourned at 2:37 p.m.